

**REMARKS**

The application includes claims 1, 2, 5, 7 - 11, 13 - 17, and 19 - 32. No claims are presently amended. Claim 33 is added herewith.

New claim 33 is added to particularly claim an embodiment of the invention. It is supported, for example, at paragraphs [0001] and [0029] of the application as published, particularly the following disclosure: "it is important that the raw material is dried before the extraction and that the extraction is carried out in a dry solvent. Otherwise, the product will be somewhat water-soluble, and obtaining the extract of the invention will necessitate expensive and complicated processes for removing the water-soluble portions of the extract".

*Claim rejections***35 USC 35 § 103**

All the pending claims were rejected as being obvious over Fuhrman et al in view of Sha et al (US 6,280,776). The Examiner reiterated the obviousness rejections of the former Office Action, stating that Applicant's arguments are not persuasive.

Applicant respectfully submits herewith a declaration made by Prof. Vaya in support to Applicant's arguments. In the following, reference is made to the declaration where evidence may be necessary.

**Combining Sha et al with Fuhrman et al is against common sense of a person skilled in the art**

The Examiner states that "it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the licorice extract disclosed by Sha et al with that disclosed by Fuhrman et al because one of skill would have been motivated to minimize LDL oxidation in Sha et al to achieve enhanced expected results of lowering the risk factors and conditions of these problematic diseases associated with LDL oxidation."

Applicant respectfully traverses. Applicant respectfully submits that replacing the licorice extract disclosed by Sha et al with that disclosed by Fuhrman et al is non-obvious and against the common sense of a person of ordinary skill in the art, for the reasons set forth in the Declaration of Prof. Vaya, and in particular, those summarized below.

First, Sha explains that the main active ingredient in licorice is glyzorrhizinic acid. Fuhrman's extract is free of glyzorrhizinic acid. It is against common sense to take constituent X of

a successful composition, and replace it with a constituent Y, that is free of the main active ingredient in X. There is actually no sense in doing so.

Second, in laboratory tests run by Prof. Vaya it was found that a water soluble licorice extract is practically free of glabridin, which is reported by Fuhrman to be the active ingredient of the water-insoluble extract. This makes the replacement of one extract with the other even less sensible.

Third, a person of ordinary skill would expect Fuhrman's extract and Sha's extract to be different not only in content of glyzorrhizinic acid, but in all, or at least nearly all, their constituents. Therefore, there is no reason to believe that the effect of one of them will be similar to the effect of the other, even if glyzorrhizinic acid is irrelevant to the efficacy of Sha's extract.

Thus, Applicant respectfully submits that the obviousness rejection is rebutted.

**Composition's shelf-life**

The Examiner notes that Sha et al teach away from selecting for water insoluble licorice extract. However, the Examiner states that "one skilled in the art would have been motivated to select for insoluble licorice extract because Sha et al teach that they use licorice extract in dry forms and to use an insoluble licorice extract one of skill would have been motivated because in this insoluble form the compound would have been expected to have a longer shelf life". Applicants respectfully traverse.

First, Applicant respectfully submits that it has been established that "it is improper to combine references where the references teach away from their combination" (See MPEP 2146 X D 2). In this respect, the Examiner is also respectively referred to the Supreme Court Opinion given in the case of KSR INT'L Co. vs. TELEFLEX INC. (hereinafter KSR), where it is stated that "the court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious" (page 12 of the opinion). Thus, Applicant respectfully submits that, since Sha et al teach away from using Fuhrman's extract, the cited combination is *prima facie* non-obvious.

In addition, the Examiner is respectfully referred to the Declaration, where Prof. Vaya declares that "shelf-life of plant extracts is not correlated with their water solubility". Thus, one of ordinary skill in the art would not expect lengthening the shelf-life of a product by replacing a water soluble ingredient with a water insoluble one; unless there is specific information suggesting that the replacement at issue would indeed lengthen the shelf-life.

Furthermore, Prof. Vaya declares that "even if one component has a longer shelf-life than another, a person of ordinary skill would not suggest exchanging between the two if they have as vastly different chemical constitution as the extracts of Sha and Fuhrman have".

Thus, Applicant respectfully submits that no valid motivation was shown by the Examiner to contradict the noted teaching away, and that no *prima facie* case has been set forth by the Examiner, and that even if it had been set forth, it is now rebutted by the Declaration.

**The rationale of obvious to try**

The Examiner further stated that "it would have been obvious to try another licorice extract which has already been used by Sha et al for the very same intended use".

Applicants are puzzled. The licorice extract that has already been used by Sha et al for the same intended use is water-soluble. The claim recites a water-insoluble extract. Thus, Applicants fail to understand the rejection as phrased.

If, however, the Examiner wanted to establish that it would have been obvious to try to replace the extract of Sha et al. with that of Fuhrman, Applicants respectfully traverse.

Obvious to try had been long considered invalid grounds for rejecting a claim under U.S.C. 103. However, in KSR the court decided that in some particular cases, an obvious to try rationale may be valid: "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense".

The Examiner has not shown any problem, the solving of which constituted a "design need or market pressure" for replacing Sha's extract with Fuhrman's. Nor did the Examiner identify any finite number of identified, predictable solutions. Therefore, no *prima facie* case of obvious to try has been set forth.

Furthermore, as proved by the Declaration, there was market pressure in the opposite direction, see paragraph 18 of the declaration, in which Prof Vaya declares that "Sha's extract is very well known in my field, and has been used in folklore medicine for centuries. It is commercially available and being important component in the American Cigarette Blend, and may be marketed without posting any unexpected regulatory problems. Fuhrman's extract, on the other hand, is not so well known, and the regulatory authorities may be expected to post heavier requirements before allowing its marketing. Therefore, I believe that market forces join the other factors I explained above in challenging the desirability of the suggested replacement."

Thus, Applicants respectfully submit that no prima facie case of obviousness was set forth by the Examiner, and even it has been set forth, it is rebutted by the Applicant.

The Examiner's rationale of similarity between Fuhrman's and Applicant's extract

The Examiner states that "Applicant admits that the licorice extract of Fuhrman et al is identical to their licorice extract and the results of lowering certain risk factors and treating conditions would have been intrinsic because it is the same extract which is being administered to a patient. No other result would have been expected to be obtained other than a successful one".

Applicant respectfully submits that the claimed risk factors and conditions are usually treated with medications that are different from those that are regularly used to treat the risk factors and conditions that Fuhrman described to treat with her extract. Therefore, Fuhrman could not have established an expectation to succeed with the claimed invention. Applicant encloses a declaration by Prof. Aviram, to testify on these matters.

In view of the above explanations and evidence, Applicant respectfully submits that the claims are in condition for allowance.

Respectfully submitted,



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Encls:

- Petition for Extension (1 Month)
- Declaration of Prof. Vaya
- CV of Prof. Vaya
- Declaration of Prof. Aviram
- CV of Prof. Aviram